

REMARKS

Claims 1-143 are currently pending. Non-elected claims 31-112 and 120-135 have been cancelled. Claims 6, 19, 113, 116, 118, 136, and 139-141 are amended herein. Claims 144-148 have been added. The specification has been amended to remove hyperlinks from the paragraph beginning on page 41, line 12 and the paragraph beginning on page 42, line 3. Claims 6, 116, 118, 136, and 141 have been amended to remove the phrase "characterized as." Claim 136 has also been amended to incorporate language from canceled claim 56, to which claim 136 referred. Claim 139 has been amended to replace "vaccine" with "composition." Claim 113 has been amended to specify that the sporulated oocysts are wild type. Claim 140 has been amended to change "comprising" to "comprises." Support for new claims 144-145 can be found on page 30, line 23 of the specification which indicates that an anti-foaming agent, such as Antifoam A, may be added during sporulation. Support for new claim 146 can be found on pages 34-36 of the specification which describe the separation of sporulated oocysts from the sporulation medium by tangential flow filtration. Support for new claim 147 can be found on pages 24, 27, 34-36, and 38-39 of the specification, which describe the use of tangential flow filtration.

Objections to the Specification

The Office has objected to the specification on pages 41 and 42 under MPEP §608.01 as containing an embedded hyperlink. Applicants have amended the paragraph beginning on page 41, line 21 and the paragraph beginning on page 42, line 3 of the specification to remove the embedded hyperlinks. Applicants thus respectfully request withdrawal of the objection to the specification in light of these amendments.

Objection to Claim 19

The Office has objected to claim 19 as failing to contain a "." Claim 19 has been amended to correct this omission. In light of this amendment, applicants respectfully request withdrawal of the objection to claim 19.

Objections to the Drawings

Attached to the Office action was form PTO-948 Notice of Draftsperson's Patent Drawing Review, indicating certain defects in Figures 1-4. Accompanying this response is a letter to the Official Draftsperson attaching revised Figures 1-5.

Rejections under 35 U.S.C. §112, second paragraph

Reconsideration is requested of the rejection of claims 6 and 136 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the Office has objected to the use of the phrase "substantially free."

The definiteness of claim language is analyzed, not in a vacuum, but in light of the content of the application disclosure.¹ In addition, "[t]he fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph...Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification."²

The full phrase as used in claims 6 and 136 is "substantially free of alkali metal dichromate." The specification has clearly defined this phrase, stating "As used herein, the term substantially free of alkali metal dichromate indicates that no alkali metal dichromate is added to the composition during production, including the sporulation and

¹ MPEP §2173.02.

² MPEP §2173.05(b).

storage of said composition. "³ One of ordinary skill in the art would thus understand what is meant by the phrase "substantially free of alkali metal dichromate," in light of the definition provided by the specification. Applicants thus respectfully submit that the phrase "substantially free" in claims 6 and 136 is not indefinite.

Reconsideration is requested of the rejection of claims 113-119 and 136-143 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the Office has objected to the phrase "characterized as" in claims 116, 118, and 141.

Claims 116, 118, 136, and 141 have been reworded to remove the phrase "characterized as." In addition, claim 6 also contained the phrase "characterized as," and has been similarly amended. Applicants respectfully note that claims 113-115, and 117 do not contain the phrase "characterized as," and are not dependent on a claim containing this phrase. Thus, there appears to be no basis for the rejection of claims 113-115, and 117 on this ground.

Reconsideration is requested of the rejection of claims 136-143 as having insufficient antecedent basis for "vaccine."

Applicants have amended claim 139 to replace "vaccine" with "composition." Antecedent basis for "composition" is found in the preamble to claim 139. With regard to claims 136-138 and 140-143, applicants respectfully note that these claims do not contain the word "vaccine," and are not dependent on claim 139. Thus, there appears to be no basis for the rejection of claims 136-138 and 140-143 on this ground.

³ Specification, p. 6, ln. 3-5.

In light of the foregoing, applicants request withdrawal of the rejection of claims 6, 113-119, and 136-143 under 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1-15, 19-23, 113-119, and 136-142 under 35 U.S.C. §102(b) as anticipated by Murray, et al. (U.S. Patent No. 4,639,372).

Claims 1, 9, and 10 are directed to a composition for the prevention or control of coccidiosis. The composition comprises viable wild type sporulated oocysts of at least one species of protozoa known to cause coccidiosis, wherein the composition is sterile. The composition of claim 1 contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate. The composition of claim 9 contains at least about 300 oocysts per milliliter and less than about 0.002% by weight of alkali metal dichromate. The composition of claim 10 contains less than about 5.0×10^{-3} µg of alkali metal dichromate per oocyst.

Amended claim 113 is directed to a kit for the prevention or control of coccidiosis. The kit comprises: (1) a composition containing sterile, viable, wild type sporulated oocysts of at least one species of protozoa known to cause coccidiosis and less than about 0.8% by weight of alkali metal dichromate; and (2) instructions for administration of the composition to an animal.

Claim 136 is directed to a composition for the prevention or control of coccidiosis. The composition comprises viable wild type sporulated oocysts of at least one species of protozoa known to cause coccidiosis, and is substantially free of alkali metal dichromate.

Murray, et al. disclose extracts from sporozoites or sporulated oocysts of *E. tenella* that may contain immunogenic polypeptides. The extracts and/or immunogenic polypeptides induce high levels of protective immunity, and may be used as a vaccine against coccidiosis. The sporulated oocyst extract may be prepared by isolating cecal cores of *Eimeria tenella* oocysts from infected chickens, partially purifying the oocysts,

incubating the oocysts in Clorox (5.25% sodium hypochlorite), removing the sodium hypochlorite by washing in sterile phosphate-buffered saline (PBS), and sporulating the oocysts in a shaking water bath.⁴ The sporulated oocysts may then be stored in PBS. A suspension of purified sporulated oocysts (5×10^7 /ml PBS) may then be ground to produce post-grind supernatant.⁵

MPEP §2131 states that a claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

Independent claims 1, 9, 10, and 136 are all directed to compositions for the prevention or control of coccidiosis comprising viable wild type sporulated oocysts. Claim 113, directed to a kit for the prevention or control of coccidiosis comprising a composition and instructions, has been amended to specify that the composition contain sterile, viable, wild type sporulated oocysts. Example 1 of Murray, et al. describes the preparation of post-grind supernatant from sporulated oocysts. Although Example 1 of Murray, et al. indicates that the oocysts used therein are *Eimeria tenella* oocysts, Murray, et al. do not indicate what type of oocysts are isolated from the chickens. Rather, Murray, et al. merely indicate the oocysts are "isolated from chickens infected 7 days earlier."⁶ Specifically, Murray, et al. do not describe the use of wild type oocysts. Since the type of oocysts is not specified, Murray, et al. could have been using other types of oocysts, such as attenuated strains. Murray, et al. can thus not be said to describe each and every element of claims 1, 9, 10, 113, and 136.

The Office has also indicated that a package insert, such as instructions, does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product,

⁴ U.S. Patent No. 4,639,372, col. 3, ln. 6-25.

⁵ *Id.* at ln. 26-27.

⁶ *Id.* at ln. 7-8.

composition of matter or article of manufacture. The Office has further indicated that "instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly no functional relationship exists between the instructions for use and the composition." "[T]he instructions for use included in composition constitute an 'intended use' for that composition."

Applicants submit that the instructions in the kit of claim 113 constitute more than a mere intended use; they are functionally related to the composition, and therefore should be given patentable weight.⁷ Claim 113 is directed to a kit for the prevention or control of coccidiosis, comprising a composition containing sterile, viable, wild type sporulated oocysts and less than about 0.8% by weight of alkali metal dichromate, and instructions for administration of the composition to an animal; applicants are not claiming the composition or instructions alone. Furthermore, the vaccine compositions of the present invention may be administered by a variety of routes, and may require dilution before administration.⁸ The instructions in claim 113 are for administration of the composition to an animal, and are thus functionally related to the composition since they allow the user of the kit to gain the additional benefit of a properly prepared and administered composition.

⁷ "Under section 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole." *In re Gulack*, 217 USPQ 401, 403 (Fed. Cir. 1983). Furthermore, "[t]he fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination." *In re Miller*, 164 USPQ 46, 49 (C.C.P.A. 1969).

⁸ "The vaccine may be concentrated, requiring dilution before administration, or the vaccine may be ready for administration. The concentrated embodiment of the instant invention may be diluted with any suitable diluent to concentrations suitable for various forms of administration, including intra-yolk sac administration, per os, oral gavage, delivery via spray cabinet, or top-fed via spray onto food, such as OASIS Hatchling Supplement." Specification, p. 46, ln. 15-20.

In addition, Murray, et al. do not disclose a kit comprising a composition containing sporulated oocysts and instructions for administration of the composition to an animal. Murray, et al., as previously discussed, do not even describe a composition with viable, wild type sporulated oocysts, as required by amended claim 113. Furthermore, it would not be obvious to combine the sporulated oocyst suspension of Murray, et al. with instructions to form a kit for the prevention or control of coccidiosis since, as previously discussed, Murray, et al. are concerned with obtaining and providing immunogenic polypeptides and extracts that may be used as a coccidiosis vaccine,⁹ and do not administer compositions comprising viable sporulated oocysts to animals.¹⁰

In light of the foregoing, applicants respectfully request withdrawal of the rejection of claims 1, 9, 10, 113, and 136 under 35 U.S.C. § 102(b). Claims 2-8, 14-15, and 19-23 are either directly or indirectly dependent on claim 1; claims 11-13 are either directly or indirectly dependent on claim 10; claims 114-119 are either directly or indirectly dependent on claim 113; and claims 137-142 are either directly or indirectly dependent on claim 136. These claims are patentable for the same reasons as the independent claim from which they depend.

In addition, the compositions of dependent claims 138 and 139 comprise sporulated oocysts of *Eimeria acervulina*, *Eimeria maxima*, and *Eimeria tenella*. As previously discussed, the oocysts used in Example 1 of Murray, et al. are *Eimeria tenella* only. Murray, et al. thus does not disclose a composition comprising sporulated oocysts of *Eimeria acervulina*, *Eimeria maxima*, and *Eimeria tenella*. Claims 138 and 139 are thus also patentable for this additional reason.

⁹ U.S. Patent No. 4,639,372, col. 1, ln. 38-50. See also *id.*, at col. 3-4 (Example 1) (describing the preparation of post-grind supernatant from a suspension of sporulated oocysts and the identification of polypeptides isolated from the post-grind supernatant).

¹⁰ *Id.* at col. 5, ln. 44-46 (Example 3) and col. 6, ln. 18-20 (Example 4) (emphasis added) ("These results show that PGS, an extract from *E. tenella* sporulated oocysts, which contains no viable or intact parasites, can be used to immunize chickens...").

Furthermore, the Office has appeared to misinterpret claims 23 and 142. The Office has stated that "[c]laim limitations such as 'the composition ameliorates a decline or decrease in post-challenge performance' ... are being viewed as a limitation of intended use."

Claim 23 (dependent on claim 14) and claim 142 (dependent on claim 137) are directed to compositions which further comprise, as a component thereof, a composition which ameliorates a decline or decrease in post-challenge performance (i.e. an ameliorating composition).¹¹ The phrase "which ameliorates a decrease [or decline] in post-challenge performance" does not specify a mere use of the composition as a whole, but instead defines an additional component of that composition by a functional characteristic which that component possesses. Such "ameliorating composition" is a component that is included in the sporulated oocyst-containing compositions of claims 14 and 137, respectively, to provide the compositions claimed in claims 23 and 142. By contrast, such an ameliorating composition is not present as a component of the sporulated oocyst suspension in Example 1 of Murray, et al. Rather, the sporulated oocysts described in Example 1 of Murray, et al. are merely suspended in PBS. Murray, et al. can not be said to describe any vaccine composition comprising viable, wild type sporulated oocysts, much less any vaccine composition further comprising a composition that ameliorates a decrease or decline in post-challenge performance. Claims 23 and 142 are thus patentable for this further reason.

In addition, the Office has appeared to misinterpret claim 139. The Office has stated that "[c]laim limitations such as...'a ratio is defined by the minimum immunizing dose and amount determined by storage half-life determinations' are being viewed as a limitation of intended use."

¹¹ See Specification, p. 44 for a description of compositions which ameliorate a decrease in post challenge performance.

Claim 139 (dependent on claim 137) is directed to a composition wherein the composition comprises viable wild type sporulated oocysts of *E. acervulina*, *E. maxima*, and *E. tenella* in a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations. The phrase "in a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" does not specify a mere intended use of the composition as a whole, but instead defines the ratio and amount of *E. acervulina*, *E. maxima*, and *E. tenella* sporulated oocysts that are present in the composition. For example, the specification indicates that the sporulated oocysts are present in a composition in a number sufficient to comprise a minimum immunizing dose.¹² Since a certain number of sporulated oocysts cease to be functional as they age, the minimum immunizing dose may be computed a function of half-life determinations.¹³

In contrast, Murray, et al. do not describe any ratio of *E. acervulina*, *E. maxima*, and *E. tenella* sporulated oocysts present in their composition. In fact, as previously discussed, Murray, et al. do not disclose a composition comprising sporulated oocysts of *Eimeria acervulina*, *Eimeria maxima*, and *Eimeria tenella*; the oocysts used in Example 1 of Murray, et al. are *Eimeria tenella* only. Furthermore, Murray, et al. do not discuss the aging of sporulated oocysts or determining a suitable amount of oocysts by storage half-life determinations. In fact, such a determination would likely be immaterial to Murray, et al., since Murray, et al. are concerned with immunizing chickens with sporulated oocyst

¹² "The combined species of sporulated oocysts are present in a number sufficient to comprise the minimum number of sporulated oocysts required to comprise an effective dose for immunizing purposes." Specification, p. 45, ln. 18-21.

¹³ "The number of sporulated oocysts per dose is further determined by the estimated half-life of the sporulated oocysts in the storage composition claimed herein. As the sporulated oocysts age a certain number cease to be functional...Therefore, a minimum amount of a single species or combination of sporulated oocysts is added to the compositions for consumption that will result in the minimum immunizing dose computed as a function of half-life determinations. *Id.* at ln. 21-27.

extracts containing antigenic polypeptides, not with a composition containing viable sporulated oocysts.¹⁴ Murray, et al. can thus not be said to describe all the limitations of claim 139. Claim 139 is thus also patentable for this further reason.

New claims 144-148 likewise are submitted to be patentable under 35 U.S.C. §102(b) over Murray, et al.

New claim 144 and dependent claim 145 are directed to compositions comprising viable, sporulated oocysts of at least one species of coccidial protozoa, and an anti-foaming agent. The sporulated oocyst suspension described in Example 1 of Murray, et al. does not contain an anti-foaming agent. Thus Murray, et al. does not describe each and every element of new claims 144 and 145.

New claims 146 and 147 are directed to compositions comprising viable sporulated oocysts of at least one species of protozoa known to cause coccidiosis. In claim 146, the oocysts have been separated by tangential flow filtration from an aqueous sporulation medium. In claim 147, the composition is sterile, and the oocysts have been separated by tangential flow filtration from an aqueous medium containing bacterial contaminants.

As disclosed in the specification of the present invention, tangential flow filtration can be used to separate the sporulated oocysts from other material that may be present in the suspension, including other microorganisms.¹⁵ Specifically, the specification states that "[t]he pore size of the filter membrane should be small enough so that sporulated

¹⁴ See Example 1 of U.S. Patent No. 4,639,372 (describing the preparation of a sporulated oocyst suspension, the grinding of the sporulated oocyst suspension to form post-grind supernatant (PGS), and the processing of the PGS to separate the polypeptides). See also *id.* at col. 5, ln. 44-46 (Example 3) and col. 6, ln. 18-20 (Example 4) ("These results show that PGS, an extract from *E. tenella* sporulated oocysts, which contains no viable or intact parasites, can be used to immunize chickens...").

¹⁵ Specification, p. 34, ln. 29 to p. 35, ln. 1.

oocysts cannot enter the pores, but large enough to allow bacteria to pass through."¹⁶ Thus, by using tangential flow filtration (under the conditions described in the specification) to separate oocysts from an aqueous sporulation medium (claim 146) or from an aqueous composition containing bacterial contaminants (claim 147), both viable and non-viable contaminants such as bacteria or other microorganisms can be removed from the oocysts. In contrast, in Murray, et al., a disinfectant (sodium hypochlorite) is removed from the oocyst suspension by several washes in phosphate-buffered saline (PBS). In this case, it would be expected that the resulting oocyst-containing composition would contain a greater proportion at least of non-viable contaminants than would be present had tangential flow filtration been used. The compositions of claims 146 and 147 thus contain fewer contaminants, such as non-viable bacterial contaminants, than they would where tangential flow filtration is not used.

Since Murray, et al. do not describe or suggest the use of tangential flow filtration in the preparation of the sporulated oocyst suspension described in Example 1, the sporulated oocyst suspension of Murray, et al. would be expected to contain at least more non-viable contaminants than would the compositions of claims 146 or 147. Thus, Murray, et al. do not describe each and every element of claim 146 or 147, and specifically, do not describe a composition wherein oocysts have been separated by tangential flow filtration from an aqueous sporulation medium or an aqueous medium containing bacterial contaminants, respectively.

Claim 148 is directed to a composition for the prevention and treatment of coccidiosis. The composition comprises a pharmaceutically acceptable carrier, diluent, or excipient; and viable, wild type, sporulated oocysts of at least one species of protozoa known to cause coccidiosis; wherein the sporulated oocysts are sterile, and the composition is substantially free of potassium dichromate.

¹⁶ *Id.* at p. 35, ln. 5-6.

As previously discussed, Murray, et al. does not describe the use of wild type oocysts. Thus, Murray, et al. does not describe each and every element of claim 148.

In light of the foregoing, applicants respectfully request withdrawal of the rejection of claims 1-15, 19-23, 113-119, and 136-142 under 35 U.S.C. §102(b), and allowance of these and new claims 144-148.

Rejections under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-15, 19-23, 113-119, and 136-143 under 35 U.S.C. §103(a) as unpatentable over Murray, et al. (U.S. Patent No. 4,639,372), in view of Brown, et al. (U.S. Patent No. 6,019,985).

Brown, et al. is apparently relied on primarily as suggesting the incorporation of *P. acnes* into the vaccine formulation of Murray, et al. It is noted that, of the rejected claims, only claim 143 actually requires the presence of *P. acnes*, despite the Office's apparent impression that this feature is present in all of the claims subject to the §103 rejection. The compositions of claim 23 and 142 further comprise a composition which ameliorates a decline or decrease in post-challenge performance,¹⁷ but does not affirmatively require *P. acnes*.

In any event, it is respectfully submitted that all of claims 1-15, 19-23, 113-119, and 136-143 are patentable over Murray, et al., and over any combination of Murray, et al. with Brown, et al.

Murray, et al. is described above. Brown, et al. disclose methods for immunization against coccidiosis and other bacterial, viral, or parasitic diseases in poultry. The methods include administering a solution of *Propionibacterium acnes* suspended in a diluent, such as normal saline, to a chick in ovo or following hatching.¹⁸ Other materials,

¹⁷ *P. acnes* is one example of such an ameliorating composition. See Specification, p. 44.

¹⁸ U.S. Patent No. 6,019,985, col. 3-4.

such as antibiotics (e.g. gentamicin, ceftiofur, and erythromycin), vaccines, vitamins, growth media, etc. may also be added to the diluent.¹⁹ Hatched chicks may also be administered an anti-coccidial vaccine, such as IMMUCOX[®] anticoccidial vaccine or COCCIVAC[®] anticoccidial vaccine,²⁰ in combination with the *P. acnes* suspension.

Where a single reference (or a combination of references) is relied on for a §103 rejection, the Office must show: (1) some suggestion or motivation, either in the references themselves, in the knowledge generally available to one of ordinary skill in the art, or in the nature of the problem to be solved²¹ to modify the reference or to combine reference teachings; (2) a reasonable expectation of success; and (3) that the prior art reference (or references when combined) teach or suggest all the claim limitations.

As discussed above, Murray, et al. do not describe or suggest suspensions of wild type sporulated oocysts. Thus, even if one were to add a composition comprising *P. acnes* (e.g. *P. acnes* in a diluent) as taught by Brown, et al. to the sporulated oocysts suspensions of Murray, et al., as the Office suggests, this combination would not satisfy all the limitations of any of claims 1-15, 19-23, 113-119, or 136-143. More specifically, the combination of Murray, et al. and Brown, et al. does not suggest compositions (or kits) for the prevention or control of coccidiosis comprising viable, wild type sporulated oocysts. The same may also be said for new claim 148, which is also directed to a composition which comprises viable, wild type, sporulated oocysts.

In light of the foregoing, applicants respectfully request withdrawal of the rejection of independent claims 1, 9, 10, 113, and 136 under 35 U.S.C. §103(a). Claims 2-8, 14-15, and 19-23 are either directly or indirectly dependent on claim 1; claims 11-13 are either directly or indirectly dependent on claim 10; claims 114-119 are either directly or indirectly dependent on claim 113; and claims 137-143 are either directly or indirectly

¹⁹ *Id.* at col. 4, ln. 7-14.

²⁰ *Id.* at ln. 59-67.

²¹ Ruiz v. A.B. Chance Co., No. 03-1333 (Fed. Cir. Jan. 29, 2004).

dependent on claim 136. These claims are patentable for the same reasons as the independent claim from which they depend.

New claims 144-148 are likewise submitted to be patentable under 35 U.S.C. §103(a) in light of Murray, et al. and Brown, et al.

Claim 144 and dependent claim 145 are directed to compositions comprising viable, sporulated oocysts and an anti-foaming agent. As previously discussed, the sporulated oocyst suspension of Example 1 of Murray, et al. does not contain an anti-foaming agent. The *P. acnes* solution of Brown, et al. likewise does not contain an anti-foaming agent. Neither Murray, et al. nor Brown, et al. suggest any need or purpose for including an anti-foaming agent. Thus, the combination of Murray, et al. and Brown, et al. cannot be said to teach or suggest all the limitations of claims 144 or 145. Claims 144 and 145 are thus patentable for this additional reason.

Claims 146 and 147 are directed to compositions comprising viable sporulated oocysts, wherein the oocysts have been separated by tangential flow filtration from an aqueous sporulation medium or from an aqueous medium containing bacterial contaminants, respectively. As previously discussed, Example 1 of Murray, et al. does not describe the use of tangential flow filtration in the preparation of the sporulated oocysts suspension. Likewise, Brown, et al. does not describe the use of tangential flow filtration. Thus, the combination of Murray, et al. and Brown, et al. cannot be said to teach or suggest all the limitations of claims 146 or 147. Claims 146 and 147 are thus patentable for this additional reason.

In light of the foregoing, applicants respectfully request withdrawal of the rejection of claims 1-15, 19-23, 113-119, and 136-143 under 35 U.S.C. §103(a), and allowance of these and new claims 144-148.

It is noted that although claims 16-18 and 24-30 have been rejected, the Office has not set forth a specific ground of rejection for these claims, as required by MPEP §

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707.07(d).²² However, since claims 16-18 and 24-30 are either directly or indirectly dependent on independent claim 1, they would also be patentable for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

²² "Where a claim is refused for any reason relating to the merits thereof it should be 'rejected' and the ground of rejection fully and clearly stated, and the word 'reject' must be used. The examiner should designate the *statutory basis* for any ground of rejection by express reference to a section of 35 U.S.C. in the opening sentence of each ground of rejection..." (emphasis in original).

CONCLUSION

In light of the foregoing, applicants respectfully request withdrawal of the rejection of claims 1-30, 113-119, and 136-143, and allowance of these claims, claims 16-18 and 24-30, and new claims 144-148.

If the Examiner has any questions, or would like to discuss any matters in connection with this response, she is invited to contact the undersigned attorney.

Please charge any required fees, if any, to Deposit Account No. 19-1345.

Respectfully submitted,



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